IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 2 CASES IDENTIFIED IN PLAINTIFFS' EXHIBIT A	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE GENERAL OPINIONS OF BRIAN J. FLYNN, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Defendants") submit this response in opposition to Plaintiffs' motion to exclude the general opinions of Brian J. Flynn, M.D. (Doc. 2130).

INTRODUCTION

Dr. Flynn is a urogynecologist focusing on treating incontinence, prolapse, and other pelvic floor disorders. Ex. A hereto, Curriculum Vitae. He has been board-certified in Urology since 2004, and he received a subspecialty certification in Female Pelvic Medicine and Reconstructive Surgery in 2014. Dr. Flynn practices in Colorado, where he serves as Associate Professor of Surgery/Urology at the University of Colorado School of Medicine and Co-Practice Director of Women's Pelvic Health and Surgery with the University of Colorado Hospital. *Id.*

Dr. Flynn has performed over 1000 surgical procedures for the treatment of stress urinary incontinence ("SUI"). Although he has used Burch colposuspension and pubovaginal slings, he has implanted over 800 midurethral slings (primarily using Ethicon's products). Ex. B to Pl's Motion, TVT Report at 2-3; Ex.G to Pl's Motion, 4/19/16 Dep. at 127:24-25. He also has

performed approximately 200 pelvic organ prolapse procedures using Prolift or Prolift +M, and he has taught fellows and residents how to implant those devices as well as how to perform other prolapse procedures. Ex. E to Pl's Motion, Prolift Report at 2; Ex. H to Pl's Motion, 4/14/16 Dep. at 216:7-14. Dr. Flynn also performs approximately 50 revision procedures each year. Ex. B hereto, 1/7/15 Dep. at 97:23-101:4.

Dr. Flynn reviews articles for four urology/urogynecology journals, and he has published articles about reconstructive urologic surgery. Ex. A hereto, CV. He trains and instructs physicians and medical school students about pelvic medicine and reconstructive surgery, he has helped create instructional videos on Defendants' products, and he has presented both nationally and internationally about these issues. Ex. B to Pl's Motion, TVT Report at 2.

In these cases, Dr. Flynn intends to offer opinions generally addressing the utility and safety of Defendants' TVT, TVT-O, TVT-Secur, Prolift and Prolift +M devices. His opinions are based upon his education, medical training, clinical experience, extensive review of medical literature, position statements, guidelines, practice patterns, curricula, and various other material reflected in his reliance list. Ex. B-F to Pl's motion at 1; Ex. K to Pl's Motion, Reliance List. Although Plaintiffs have challenged certain aspects of Dr. Flynn's opinions, as set forth below, he is qualified to opine on these topics and his opinions are supported by a reliable methodology.

ARGUMENT

Defendants incorporate by reference the standard of review for *Daubert* motions as articulated by the Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D. W. Va. 2014).

I. Plaintiffs' brief is untimely.

The Court granted Plaintiffs an extension until May 5, 2016, in which to challenge Dr. Flynn's general opinions. *See, e.g.,* Case No. 2:12-cv-1021, Doc. 130. Although Plaintiffs filed

their motion on May 5, 2016 (Doc. 2130), Plaintiffs did not file their supporting memorandum until May 6, 2016. Doc. 2131.

II. Dr. Flynn's opinions are supported by a reliable methodology.

A. Dr. Flynn performed a thorough review of the literature.

Plaintiffs misleadingly state that "Dr. Flynn admitted that he did not perform a systematic review of the relevant scientific literature." Doc. 2131, p. 3. In support of this assertion, Plaintiffs only cite testimony by Dr. Flynn about his review of literature in preparing his Prolift and Prolift +M reports. *Id.* (citing Ex. H to Pl's Motion, 4/14/16 Prolift Dep. at 2:18-19, 60:3-12).[1] Plaintiffs have taken Dr. Flynn's testimony out of context. Dr. Flynn merely indicated that his Prolift report, itself, would not be considered a "systematic review"; he did not suggest that he never performed a comprehensive review in formulating his opinions and summarizing those opinions in his report.

According to Dr. Flynn, he prepared a reliance list (Ex. K to Pl's motion) following a broad PubMed research search performed with the same methodology that he would use for his clinical practice or publications. Ex. H to Pl's Motion, 4/14/16 Prolift Dep. at 23:21-25:1, 58:8-59:13, 208:22-209:4.[2] That search appears to have been extraordinarily comprehensive, as Dr. Flynn's reliance list includes hundreds of references in the medical literature. Ex. K to Pl's motion. According to Dr. Flynn:

> A. . . . If you look at the levels of evidence for practitioners, 6 you have Level I evidence, which would be the highest level that is systematically used, meta-

[1] Plaintiffs cite no evidence in support of their suggestion that Dr. Flynn failed to perform a sufficient review of the literature associated with TVT, TVT-O or TVT-Secur, and therefore, Plaintiffs have not properly challenged Dr. Flynn's opinions about those devices.

[2] Dr. Flynn testified that it is his general practice to read scientific articles that affect his practice; that he typically reads a number of journals; that he belongs to a journal club as part of his medical practice, which meets multiple times a year; that he is a reviewer for a number of medical journals; and that he is "looking at the medical literature very commonly." *Id.* at 60:20-61:18. He also keeps apprised of the important medical literature by attending scientific meetings and discussing it with colleagues. *Id.* at 62:9-18.

> analyses and RCTs. And then go all the way down to the bottom of the pyramid, Level IV would be, you know, case reports, and so that would be the lowest level of evidence. In between, you have case series, and then prospective studies that are nonrandomized.
>
> Q. Okay. And you wouldn't consider your report a systematic review of the totality of literature that exists regarding Prolift, would you?
>
> A. It's not a systematic review. That's correct.
>
> Q. And likewise, you didn't perform a meta-analysis here, did you?
>
> A. I did not.
>
> Q. In fact, you're here relying upon other people's systematic reviews and meta-analyses; is that correct?
>
> A. As well as my own personal experience with this device.

Ex. H to Pl's Motion, 4/14/16 Prolift Dep. at 26:4-27:2 (emphasis added). Thus, Dr. Flynn was merely stating that he relied on systematic reviews and meta-analyses that others had conducted but that he did not consider his report, itself, to be a systematic review in the same sense as those (and no definition of "systematic review" was provided during deposition).[3]

Plaintiffs also argue that Dr. Flynn cherry-picked articles and "only included literature in his reports that supported his predetermined opinions." Doc. 2131, pp. 2-3. This is simply wrong. First, once again, Plaintiffs cite (albeit out of context) only Dr. Flynn's testimony about his Prolift reports. *Id.* at 3-4. In any event, as noted above and as reflected in his comprehensive reliance list, Dr. Flynn reviewed an enormous amount of medical literature and performed an extensive unbiased PubMed search. Ex. K to Pl's Motion, Reliance List; Ex. H to Pl's Motion,

[3] For instance, in the Society of Gynecologic Surgeons Systematic Review Group's 2014 systematic review on sling surgery for SUI in women—a study that Dr. Flynn relies on and discusses in his TVT reports—the authors describe the precise data sources they consulted, the searches they ran in those data sources, how the reviewers screened the abstracts for possible inclusion in the review, how studies were selected once they were located, how the data was extracted from studies, how the quality of the studies was assessed, and how the data was synthesized and analyzed. *See also* Exs. B, C, and D to Pl's Motion, TVT Reports at 19 (citing Tommaselli 2015 systematic review, Schimpf systematic review, and Ford Cochrane Review). Interestingly, Plaintiffs criticize Dr. Flynn for not performing a systematic review notwithstanding the fact that Plaintiffs' own experts ignore the systematic reviews demonstrating the safety and efficacy of synthetic midurethral slings.

4/14/16 Prolift Dep. at 13:9-15. This literature that Dr. Flynn reviewed and took into account includes randomized controlled trials that both reported very positive things about Prolift as well as literature that was "not-so-positive." *Id.* at 205:5-18.

In choosing which literature to cite in his Prolift report, Dr. Flynn included "articles that had been important to [him] over the last 15 years in affecting how [he] thought about prolapse and how he managed it." *Id.* at 22:17-23:2. To ensure reliability, he screened the studies so as to include "studies that are well-designed of high levels of evidence, that are from reputable peer-reviewed journals, that have a large cohort of patients, preferably multi-center, et cetera." *Id.* at 223:6-15. Notwithstanding Plaintiffs' unsupported claim that Dr. Flynn's Prolift report "only include[s]" favorable literature (Doc. 2131, pp. 2-3), Dr. Flynn stated:

> [M]any of those [unfavorable articles] are included in this report. So I felt that this was a very balanced report. Naturally, the articles that I rely on to formulate my opinions are going to be more heavily emphasized.

Id. at 24:16-25:1. Indeed, Dr. Flynn did not "cherry-pick" favorable evidence; when Dr. Flynn testified that he "tried to choose articles that support [his] opinions," he was not describing his methodology for reviewing literature, he was describing how he chose what to cite in his report. *Id.* at 20:13-24.

There similarly is no merit to Plaintiffs' accusations that Dr. Flynn "ignored" contrary evidence. There are thousands of articles published on the subject of incontinence and prolapse surgery, and the fact that Dr. Flynn has not analyzed *every single article* does not make his methodology unscientific or his opinions unreliable. Dr. Flynn explained why he relied more heavily on Level 1 evidence. *Id.* at 26:4-13. Indeed, "[a] fundamental principle of evidence-based medicine . . . is that the strength of medical evidence supporting a therapy or strategy is hierarchical. When ordered from strongest to weakest, systematic review of randomized trials

(meta-analysis) is at the top, followed by single randomized trials, systematic reviews of observational studies, single observational studies, physiological studies, and unsystematic clinical observations." *See* Federal Judicial Center, Reference Manual on Scientific Evidence 723-24. Dr. Flynn cites numerous Cochrane reviews, systematic reviews, and meta-analyses throughout his reports. *See, e.g.*, citations to studies by Ford, Schimpf, Novara, Tommaselli, Walsh, and Maher studies in Dr. Flynn's reports.[4]

The Court rejected a similar argument in *Trevino v. Boston Scientific Corp.*, 2016 WL 2939521, May 19, 2016 Slip Copy (S.D. W. Va. Apr. 28, 2016). The plaintiff in that case challenged defense expert Stephen Badylak, M.D.'s competence to testify about the safety and efficacy of polypropylene mesh devices on the basis that Dr. Badylak had admitted that he had not performed a "comprehensive review" of the scientific literature related to the defendant's devices." *Id.* at *41. The Court, however, noted that Dr. Badylak's report demonstrated that he "reviewed more than 200 relevant scientific publications, including more than twenty publications evaluating the safety and efficacy of BSC devices," and that "[i]f there are certain device-specific publications that Dr. Badylak failed to review in preparing his expert report, the plaintiff is free to ask him about those publications on cross-examination." *Id.*; *see also id.* at *5 (S.D. W. Va. Apr. 28, 2016) (finding that "to the extent the defendant challenges the reasons Dr. Margolis offers for not relying on certain studies, such challenges go to the weight of Dr. Margolis's opinions, not their admissibility" and that "[t]he defendant is free to cross-examine Dr. Margolis regarding studies that cut against his opinions").

[4] Further, "[w]ell-performed randomized trials provide the least biased estimates of treatment benefit and harm by creating groups with equivalent prognoses." Federal Judicial Center, Reference Manual on Scientific Evidence 729. Dr. Flynn included an extensive discussion of several available RCTs regarding the TVT, TVT-O, TVT-S, and Prolift in his reports on those products.

Applying the Court's reasoning to these cases, Dr. Flynn plainly has performed a sufficiently thorough review of the medical literature to ensure the reliability of his opinions. If Plaintiffs wish to nit-pick Dr. Flynn's failure to cite certain studies, cross-examination is the appropriate vehicle to do so. Indeed, if Plaintiffs held their own experts to the standard that they seek to hold Dr. Flynn, all of Plaintiffs' own experts would be disqualified in these cases. Further, if that were the standard to which the parties' experts must adhere, their reports would look like phone books rather than summaries. That is not what the law requires.

1. TVT-Secur

Plaintiffs claim that all of Dr. Flynn's opinions about the safety and efficacy of TVT-Secur are unreliable merely because his TVT-Secur report did not reference one Cochrane review. Doc. 2131, pp. 5-7. The Cochrane review cited by Plaintiffs, however, is included in Dr. Flynn's reliance list, and Dr. Flynn explained that (1) the study was on mini-slings, not just the TVT-Secur; (2) it was one of several systematic reviews that addressed the TVT-Secur; and (3) he chose to cite one of the other systematic studies in his report because it was one that he was more familiar with and better represents the TVT-Secur in his opinion. Ex. K to Pl's Motion, Reliance List; Ex. I to Pl's Motion, F3/24/16 Dep. at 79:13-81:5, 84:1-5.

Dr. Flynn did not overlook or ignore the best evidence regarding the safety of the TVT-Secur, and when directly questioned about this particular review he provided a reasoned explanation for his decision not to reference it directly in his report. When explaining why the review is not mentioned in his report, Dr. Flynn stated:

> It's not the only systematic review on TVT-Secur. And this systematic review is on mini slings. It's not just on TVT-Secur. So for instance, the Wall study in 2011 is another systematic review and meta-analysis of over a thousand patients that had a mesh exposure rate of 2.4. Tomaselli, 2013, RCT. 4 RCTs are a very high level of evidence as well, and didn't show a high exposure rate any different than TVT-O.

> So you have to look at a number of studies. I think there's always going to be one study, even possibly a systematic review that might report something different than other systematic reviews. So there's multiple systematic reviews on mini slings. I chose to cite the Wall study, and that's what I have in my report. So I did choose one of the systematic reviews. It was one that was – one that I was more familiar with.

Id. at 79:22-80:15. He also explained that although a Cochrane review referenced in his report may not have been specifically applicable to single-incision slings like the TVT-Secur, it "speaks to the safety of the mesh in the TVT-Secur." Ex. D to Pl's Motion, TVT-Secur Report at 22.

Therefore, it is not true that Dr. Flynn "without explanation" "testified that he simply disagreed with the paper's conclusion," as Plaintiffs argue at page 6 of their brief. Again, "[i]f there are certain device-specific publications that [Plaintiffs claim that Dr. Flynn] failed to review in preparing his expert report, the plaintiff is free to ask him about those publications on cross-examination." *Trevino*, 2016 WL 2939521, at *41.

2. TVT-O

Plaintiffs' specific criticisms of Dr. Flynn's TVT-O opinions also lack merit. Plaintiffs suggest that the Court should preclude Dr. Flynn from testifying that TVT-O is safe and effective, because he supposedly "testified that he no longer uses the TVT-O and, in fact, has not used one in years because, in his opinion, the TVT-Abbrevo is a better product." Doc. 2131, p. 7. Yet, Dr. Flynn explicitly refused to state that TVT-Abbrevo is "better." Ex. J to Pl's Motion, 4/14/16 TVT-O Dep. at 26:21-27:3; 40:4-12. In any event, just because Dr. Flynn may prefer TVT-Abbrevo does not mean that he believes TVT-O to be unsafe or ineffective.

Plaintiffs also incorrectly assert that Dr. Flynn opines in his report "that the TVT-O is safer than other obturator devices because the 'inside-out' approach of the TVT-O 'allows a greater distance between the implanted mesh and the obturator nerve, thereby reducing potential

complications in SUI surgery.'" Doc. 2131, p. 7. Dr. Flynn's report merely states: "The unique inside-to-out approach created by Dr. de Leval to allow [sic] a greater distance between the implanted mesh and the obturator nerve, thereby reducing potential complications in SUI surgery." Ex. C to Pl's Motion, TVT-O Report at 21. As Dr. Flynn explained in his deposition, this statement was "just generally describing why it was created and what the goals of it were." Ex. J to Pl's Motion, 4/14/16 TVT-O Dep. at 56:1-6.

Dr. Flynn reliably and appropriately explained why the Zahn, Achtari, and Spinosa studies referenced by Plaintiffs do not alter his opinions. Dr. Flynn testified that the conclusions reached by those studies (that the outside-in technique lays the mesh farther from the nerve bundle) were inconsistent with his personal experience with the TVT-O device, and "not what any of the systematic reviews or [randomized control trials] show." *Id.* at 62:15-22. He also noted that all three studies were cadaveric studies, which have "a lot of limitations" and are "not as reliable as human studies, live studies, meta-analyses, systematic reviews." *Id.* at 63:13-64:4, 64:17-22. Dr. Flynn stressed that the issue is "very controversial, so you'll have some reports say the outside-to-in is superior and others who say the inside-to-out is superior." *Id.* at 58:13-19.

Dr. Flynn's opinions about the safety and efficacy of TVT-O are well supported by his personal experiences and the medical literature. Plaintiffs' criticisms are appropriate matters for cross-examination. *Trevino*, 2016 WL 2939521, at *41.

3. Prolift and Prolift +M

Although Plaintiffs also argue that Dr. Flynn failed to take into account contrary medical literature when formulating his Prolift opinions, he has appropriately articulated his methodology and accounted for contrary literature. As it relates to the 2016 Cochrane review, Dr. Flynn testified that he was aware of the review, but he inadvertently neglected to update his reliance list

to include it. Ex. H to Pl's Motion, 4/14/16 Prolift Dep. at 171:15-172:29, 173:10-17. Although he acknowledged that the review is an "important document" and the he is aware that the review concluded that the risk of the mesh in Prolift might not be outweighed by the benefits associated with recurrence, Dr. Flynn stated that this conclusion did not change his opinion that the devices are safe and effective given the "wealth of information on a product that was very well-studied." *Id.* at 174:14-175:12, 179:11-24.

Notwithstanding Plaintiffs' assertion, this 2016 Cochrane review was not "completely contrary to Dr. Flynn's opinions." Doc. 2131, p. 10. In fact, Dr. Flynn agreed with numerous other conclusions of the 2016 review. Ex. H to Pl's Motion, 4/14/16 Prolift Dep. at 181:19-183:10. For instance, the review's findings that awareness of prolapse at 1-3 years was less likely after mesh repair and that rates of repeat surgery for prolapse were lower for mesh patients is consistent with Dr. Flynn's opinion and experience. *Id.* at 181:19-182:10. Dr. Flynn also agrees with the review's finding that there was no evidence of any difference in the rates of de novo dyspareunia between the native tissue repair patients and mesh patients. *Id.* at 183:1-10.

Dr. Flynn's reports and reliance list show that he thoroughly researched the Prolift and Prolift +M devices and considering that research. Coupling that research with his personal experience is a very sound and scientific method for formulating his opinions in these cases. The mere failure to cite one specific article—much of which is consistent with and supports his opinions—does not render his opinions unreliable or his methodology unscientific. Moreover, Dr. Flynn's reliance and discussion of the 2013 Cochrane review refutes Plaintiff's accusations that Dr. Flynn "cherry-picked" only favorable articles to review. That article notes, for instance, that "the use of mesh or graft inlays at the time of anterior vaginal wall repair reduces the risk of recurrent anterior wall prolapse on examination. Anterior vaginal polypropylene mesh also

reduces awareness of prolapse, however these benefits must be weighed against increased operating time, blood loss, rate of apical or posterior compartment prolapse, de novo stress urinary incontinence, and reoperation rate for mesh exposures associated with the use of polypropylene mesh." Ex. C hereto, at 2.

As it relates to the Stanford study referenced in Plaintiffs' brief, Plaintiffs have acknowledged that it is included in Dr. Flynn's reliance list. Ex. K to Pl's Motion, Reliance List. Moreover, Dr. Flynn testified that "[i]t's not so much that I discount the strength of this, it's that I rely more heavily on other systematic reviews that are larger that included a greater number of studies." Ex. H to Pl's Motion, 4/14/16 Prolift Dep. at 106:18-24.

As it relates to the Iglesia study, Dr. Flynn testified that he was familiar with it (and it is included on his reliance list), but that there were problems with the study because Dr. Iglesia's "ability to do a mesh-augmented repair has been called into serious question by a number of people." *Id.* at 108:4-17. He also stated that "I primarily used the systematic reviews and Cochrane reviews to formulate my opinions, and this is of a lower level of evidence, and it doesn't affect my opinions." *Id.* at 110:8-14. Similarly, Dr. Flynn is aware of the Diwadkr study, which is also on his reliance list. *Id.* at 115:16-20. After reviewing the conclusion section of the abstract, he testified that the conclusion did not affect his opinions. *Id.* at 112:2-13.

This medical literature was among numerous reviews, meta-analyses, studies, and articles that Dr. Flynn used to formulate his opinions. Cross-examination is the appropriate forum for Plaintiffs to present these arguments.

B. Dr. Flynn's personal experiences are reliable.

As set forth in the Introduction section above, Dr. Flynn has extensive personal experience with the devices at issue and with SUI and prolapse surgeries. In fact, Dr. Flynn has

published two articles regarding mesh complications that included retrospective case series analysis. Ex. A hereto, CV; Ex. D hereto, 8/29/14 Dep. at 8:23-9:22. Plaintiffs have even acknowledged that "[i]n 2013, Dr. Flynn also published an article discussing his personal experience with surgical management of mesh related complications." Doc. 2131, p. 13.

Plaintiffs claim that Dr. Flynn's opinions are somehow unreliable because he accidentally misstated in one deposition that he started using TVT-O before TVT. *Id.* at 12. As noted by this Court, "[c]ontradictions in testimony should be addressed on cross-examination," and in any event, Plaintiffs do not explain how this trivial discrepancy is of any significance. *Wilkerson v. Boston Scientific Corp.*, 2015 WL 2087048, at *11 (S.D. W. Va. May 5, 2015).

Dr. Flynn's failure to maintain a registry to track precisely his personal experiences with patients does not render his testimony unreliable. In rejecting a similar argument in another case, this Court found as follows:

> The plaintiff takes issue with Dr. Robboy's reliance on his clinical experience because she has no way of "independently verifying" opinions. The plaintiff's argument has no practical merit. Numerous expert witnesses throughout the course of these MDLs have relied on their clinical experience in forming their expert opinions. Such practice can hardly be described as a "mystery." If *Daubert* required an expert witness to independently verify every single clinical experience he had over the course of his career, the court would never make it past pre-trial motions.

Ex. E hereto, *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Doc. 265, p. 40 (S.D. W. Va. Nov. 20, 2014); *see also Winebarger*, 2015 WL 1887222, at *34 (finding that expert's inability to provide "exact statistics" about the outcome of his patients did not render his personal experience opinions unreliable and that "such detail is not required under *Daubert* to opine as to '*large-scale* safety and efficacy of the Uphold device'"); *Trevino*, 2016 WL 2939521, at *33 (same).

For these same reasons, the Court should reject Plaintiffs' argument here. Indeed, physicians routinely counsel patients considering surgery on the physicians' rough perception of

their own complication rates, and Dr. Flynn's inability to confirm his understanding of his complication rates with precisions does not render his experience unhelpful or unscientific.

Dr. Flynn did not "guess" but provided estimates of numbers. *See also* Ex. B to Pl's Motion, TVT Report at 22. He has applied a sound methodology in formulating his opinions regarding the safety and utility of the devices at issue based on his personal experience and his thorough review of peer-reviewed publications. This Court has recognized that a physician may testify that complication rates found in literature are verified by his personal experience. *See, e.g., Tyree v. Boston Scientific Corp,* 54 F. Supp. 3d 501, 585 (S.D. W. Va. 2014) (expert's opinion about safety and efficacy was reliable where opinion was based upon "minimal complications in his clinical practice" which was "'on par with the findings of [the] studies' he cites throughout his expert report"); *Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, at *12, *36 (S.D. W. Va. Apr. 28, 2015) (finding Dr. Galloway's method of considering scientific articles and drawing on his clinical experience to reach his opinion regarding degradation to be methodologically sound and allowing Dr. Culligan "by way of his experience with the Uphold device and his review of the relevant scientific literature" to opine how these procedures compare). That is precisely what Dr. Flynn will do in these cases. Any alleged inconsistencies or weaknesses in Dr. Flynn's testimony go to its weight, not its admissibility. *See Daubert,* 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence").

III. Dr. Flynn is competent to testify about degradation, warnings, and other issues.

A. Dr. Flynn's opinions about degradation are reliable.

There is no merit to Plaintiffs' argument that Dr. Flynn may not testify about degradation. Dr. Flynn is qualified to opine about degradation based on his significant clinical experience (in which he has not observed any clinically meaningful degradation), as well as his extensive review of scientific literature—including literature that Plaintiffs' experts in these cases have cited.[5] Dr. Flynn's opinions are particularly bolstered by his review of Level 1 long-term studies, RCTs, systematic reviews, meta-analyses, and Cochrane reviews demonstrating the safety of polypropylene mesh and that the mesh is not degrading. *See, e.g.*, Ex. B to Pl's Motion, TVT Report at 27; Ex. G to Pl's Motion, 4/19/16 Dep. at 65:20-70:23. As stated by Dr. Flynn: "Well, if you look at the – more than 100 RCTs and more than 1,000 articles in the peer-reviewed literature looking at clinical results of TVT and if you ask me about my own personal experience, there is no evidence of degradation in the clinical literature," with the exception of a small number of articles that he referenced. Ex. B hereto, 1/7/15 Dep. at 254:15-255:7.

Although Plaintiffs fault Dr. Flynn for not reviewing the devices' design history files, Dr. Flynn does not offer opinions about Ethicon's process for developing products. Indeed, Dr. Flynn's opinions about degradation are not at the molecular level and the equivalent of the opinions of polymer scientist, but instead, focused on clinical aspects of alleged degradation. *See Wilkerson v. Boston Scientific Corp.*, 2015 WL 2087048, at *20 (S.D. W. Va. May 5, 2015) ("That he has no experience in polymer science is irrelevant because Dr. Porter is not offering opinions about 'what's happening at the molecular level'").

[5] Dr. Flynn also has a biomedical engineering education background. Ex. A, CV.

In these MDLs, the Court has allowed urologists and gynecologists with similar qualifications as Dr. Flynn to testify about degradation. For instance, in *Trevino v. Boston Scientific Corp.*, 2016 WL 2939521, at *45, the plaintiff argued that Dr. Michael Douso, a urogynecologist, was not qualified to testify about the physical properties of mesh and to offer opinions about degradation and similar topics because he was not a biomaterials or polymer science expert. In rejecting this challenge, the Court stated as follows:

> As to qualification, Dr. Douso is a practicing urogynecologist, and he is board-certified in obstetrics and gynecology. He has extensive experience with BSC's produces for treating SUI and POP, including use of the Prefyx and Uphold mesh sling devices. Dr. Douso has had extensive experience teaching minimally invasive surgical techniques and procedures to physicians across the United States, including implantation of the defendant's polypropylene mesh devices. Simply because Dr. Douso is not an engineer, chemist, or biomechanical expert does not render him unqualified to testify that he has not experienced mesh degradation, contraction, or a foreign body response in his practice. "One knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an [expert] opinion." *Thomas J. Kline, Inc.*, 878 F.2d at 799. I **FIND** that Dr. Douso's extensive experience qualified him to testify that he has not experienced certain alleged physical properties in the defendant's Uphold and Prefyx devices.
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> * * *
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> The literature on which Dr. Douso relies includes multiple studies regarding polypropylene mesh devices and on the body's post-operative reaction to the mesh.
>
> The court has permitted physicians in related cases to offer similar opinions based on their clinical experience and review of the scientific literature. *See Tyree*, 54 F. Supp. 3d at 585 (finding an expert's "clinical experience and review of the scientific literature are sufficiently reliable bases in forming this particular opinion"). Accordingly, I **FIND** that Dr. Douso's extensive clinical experience and literature review provide a sufficient reliable basis for his opinions. The plaintiff's motion on this point is **DENIED**.

2016 WL 1718836, at *46 (other citations omitted); *see also id.* at *5 (finding that urologist Niall Galloway's "clinical experience and review of the scientific literature adequately qualify him to opine on polypropylene, including its degradation, leaching, shrinkage and contraction"); *id.* at

*33 (allowing testimony of defense expert Patrick Culligan, M.D.); *Huskey*, 29 F. Supp. 3d at 706-07, 735 (rejecting similar challenges to plaintiff expert Bruce Rosenzweig, M.D., and defense expert urogynecologist Harry Johnson, M.D.); *Tyree*, 54 F. Supp. 3d at 550, 585 (rejecting similar challenge of plaintiff expert Donald Ostergard, M.D. and defense expert Lonny Green, M.D.); *Jones v. Bard, Inc.*, No. 2:11–cv–00114, [Doc. 391], pp. 6–9.

Plaintiffs also argue that Dr. Flynn should not be allowed to testify about the lack of any meaningful clinical effects of degradation, because he has not read papers by Drs. Iakovlev or Tzartzeva. Doc. 2131, pp. 16-17. In *Huskey*, this Court rejected a similar challenge to defense expert urogynecologist, Harry Johnson, M.D. 29 F. Supp. 3d at 735. Noting that although "Dr. Johnson's opinion is not subject to testing and it is not supported by peer-reviewed literature *affirmatively* stating that degradation lacks clinical significance," Dr. Johnson's "clinical experience and his review of the scientific literature" set forth a sufficient basis for his opinion and "Dr. Johnson's failure to review particular documents goes to the weight of his opinion, not its admissibility." *Id.* Again, "[i]f there are certain device-specific publications that [Plaintiffs claim that Dr. Flynn] failed to review in preparing his expert report, the plaintiff is free to ask him about those publications on cross-examination." *Trevino*, 2016 WL 2939521, at *41.

B. Dr. Flynn's analysis of laser-cut mesh is reliable.

Although Dr. Flynn may not have expertise to address the biomaterials distinctions between mechanically-cut mesh ("MCM") and laser-cut mesh ("LCM"), he is well qualified to testify, from a clinical perspective, that there is not "any clinical significant difference between laser-cut mesh and mechanical-cut mesh in my own practice or what's reported in the literature or from conversation with colleagues." Ex. B hereto, 1/7/15 Dep. 68:1-5. Dr. Flynn will not

address biomaterials properties, but as he stated, "I'm prepared to answer questions as a physician and a clinician with respect to laser-cut and mechanically-cut." *Id.* at 65:20-22.

Dr. Flynn has used both MCM and LCM devices. Although "there's some subtle differences," they are "essentially the same" and "what the literature shows is that the products have behaved similarly based on efficacy and safety." *Id.* at 66:10; Ex. G to Pl's Motion, 4/19/16 Dep. at 121:5-9, 122:9-16; Ex B to Pl's Motion, TVT Report at 13, 21. Dr. Flynn has explained at length about how numerous studies, RCTs, and reviews have confirmed his personal experience that LCM and MCM devices have similar efficacy and safety. *Id.*; Ex. B hereto 1/7/15 Dep. at 246:11-25; Ex. G to Pl's Motion, 4/19/16 Dep. at 117:6-118:1, 122:17-123:10, 127:3-129:16. Although Plaintiffs assert that Dr. Flynn was unable to distinguish between the types of mesh used in specific studies, Dr. Flynn has persuasively pointed out: "I think if you look at the literature based on products that came only as laser cut, for instance, TVT-Secur, TVT-Abbrevo, TVT-Exact, and you compare those to the TVT studies that were published before 2006, you've just created a comparison. And at least with respect to safety . . . they performed very similarly." *Id.* at 122:17-123:6. Dr. Flynn's background, experience, and review of the literature render him well-qualified to testify that both LCM and MCM devices are safe and effective and that there is no material difference between these types of devices.

C. Dr. Flynn may reliably testify about Ethicon's product warnings.

Dr. Flynn has opined on the completeness and accuracy of the IFU warnings from a clinical perspective based on his knowledge of and clinical experience with the devices. *E.g.*, Ex. B to Pl's Motion, TVT Report at 29-33; Ex. E to Pl's Motion, Prolift Report at 33-35. Plaintiffs do not challenge, or even address, Dr. Flynn's clinical expertise. Instead Plaintiffs

argue that he is not qualified to opine on the adequacy of the IFUs because he lacks familiarity with the regulatory process governing the development of such documents.

Although Dr. Flynn does not purport to be a regulatory expert, he has considered the FDA's 1990s guidance on IFUs, and he has relied on the standards of professional societies and the standard that was taught to him as a resident fellow and that he and his peers across the country use. Ex. H to Pl's Motion, 4/14/16 Prolift Dep. at 74:16-75:2, 76:15-25. Plaintiffs do nothing but establish Dr. Flynn's lack of qualification to opine regarding FDA regulations as applied to the development of product warnings – an opinion that he has not offered. Rather, as Dr. Flynn recently testified, it is his opinion, from a clinical perspective, that "if something is considered public knowledge that a reasonable physician would know and be aware of, that you don't need to warn of that because it's not unique to the product." Ex. F hereto, 7/21/16 Dep. at 70:13-18. Under Plaintiffs' reasoning, Plaintiffs' own pelvic surgeon experts, such as Drs. Blaivas, Shull, Margolis, Elliott, and Rosenzweig, are not qualified to testify about product warnings in any form or fashion. If the Court allows Plaintiffs to elicit warnings opinions from their clinician experts, then fairness dictates that Defendants be allowed to elicit such opinions from Defendants' experts.

Dr. Flynn is qualified to testify about the completeness and accuracy of the warnings from a clinical perspective. Dr. Flynn's reports and deposition testimony detail his extensive experience with the devices, including particular risks and complications he has experienced and researched, and his reports explain his opinions in detail. *E.g.*, Ex. B to Pl's Motion, TVT Report at 29-33. Dr. Flynn has extensive expertise in analyzing warnings in IFUs and patient brochures. Ex. F hereto, 7/21/16 Dep. at 66:12-18. His extensive clinical experience with the products at issue is supplemented by an incredibly thorough review of the relevant literature and

education he has provided to others. *Id.*, *passim*; Ex. K to Pl's Motion, Reliance List. Dr. Flynn recently testified that he has prepared lectures on warnings and IFUs, has had communication directly with the FDA on the topic, analyzed position statements from IGA and AUGS, and has participated in round-table discussions with other experts on this topic. *Id*. at 69:3-13.

Although Plaintiffs claim that Dr. Flynn contradicted the standard he followed when he testified that the risk of damage to surrounding structures should be included in the IFU, even though that risk is not a risk that is unique to Prolift, Dr. Flynn clarified that the risk was unique to Prolift in terms of the graft material and the devices that are used to place the graft material (inserters or tunnelers). Ex. H to Pl's Motion, 4/14/16 Prolift Dep. at 81:2-12. He further testified that he believes that that may be standard language in IFUs for mesh kits, and that he took into account his review of other products' IFUs. *Id.* at 81:15-82:5. Although Dr. Flynn testified that he was unsure whether he had reviewed the 2015 changes to the TVT IFU, those changes *strengthened* the warnings; thus, if Dr. Flynn was satisfied with the preexisting warnings, he plainly was satisfied with the updated warnings.

Ethicon recognizes that the Court has precluded defense experts in these cases from opining that a "warning was adequate merely because it included the risks he has observed in his own practice." *Trevino*, 2016 WL 2939521 at *45. Plaintiffs do not challenge Dr. Flynn's warning opinions on this basis. Even if they did, such a challenge would lack merit. Although the Court has been clear that just because an expert had not seen a particular risk in his practice did not justify his testimony that the risk did not exist, *id.*, that is not what Dr. Flynn seeks to do here. Instead, Dr. Flynn will testify that the complications that Plaintiffs allege should have been in the IFUs: (a) are risks that a pelvic surgeon would already know, and therefore, need not be warned about; (b) are not genuine complications; or (c) are not attributable to the device.

As it relates to the latter two categories, Dr. Flynn's report and deposition show that his opinions are based on his extensive clinical experience, *as well as* his thorough critique of scientific literature. *See, e.g.,* Ex. B to Pl's Motion, TVT Report at 25-28 (explaining why he disputes that mesh causes various conditions, such as infection, inflammation, cytotoxicity, cancer, contraction, or degradation). Thus, this is sufficient to distinguish the circumstances here from *Trevino*. *See Huskey*, 29 F. Supp. 3d at 734-35 (allowing Dr. Johnson to testify about evidence of absence because his opinions were also based on medical literature); *Carlson*, 2015 WL 1931311 at *12.[6]

Moreover, Dr. Flynn, as an experienced clinician, is well qualified to testify about complications that are "commonly known" such that they need not be included in an IFU. Ex. B to Pl's Motion, TVT Report at 31. The law imposes no duty to warn sophisticated users of products with respect to risks that the sophisticated users already know or should know. *See, e.g.,* Restatement (Third) of Torts: Product Liability §2 cmt. j (1998); Restatement (Second) of the Law of Torts §402A cmt. j; American Law of Product Liability 3d § 32:69 (2016); *Willis v. Raymark Indus., Inc.*, 905 F.2d 793, 797 (4th Cir. 1990). In fact, 21 CFR § 801.109(c) states there is no duty to warn if "the article is a device for which the hazards, warnings and other information are commonly known to practitioners licensed by law to use the device."

This is an objective test not dependent on the knowledge of the individual surgeon, and Dr. Flynn is certainly competent to share his opinions about what risks should be obvious to

[6] While this Court has observed that "[a]bsence of evidence is not evidence of absence" *Tyree*, 54 F. Supp. 3d at 583-84, the observation only holds true where a cursory inquiry of the evidence has been made. For instance, if a physician is relying merely on his own experience to opine that a particular risk does not exist, the methodology may be flawed. However, where, as here, a physician examines the evidence outside of his own experience, such as by critiquing the medical literature and studying the conclusions of medical organizations, then the physician's opinions have a reliable basis. If there is no reliable evidence of risk as determined by a detailed review of appropriate sources, there is no obligation to include the risk in the IFU warnings.

surgeons who use the devices and how an average clinician would construe the IFUs. Indeed, Ethicon writes its IFUs for pelvic floor surgeons like Dr. Flynn. Under the learned intermediary doctrine, such surgeons are the ones who must be adequately warned. If Plaintiffs intend to argue at trial that Ethicon's IFUs failed to disclose certain risks, then it is only fair that Ethicon be allowed to defend itself by demonstrating that those risks were obvious to the users of the product (pelvic surgeons and urologists), and therefore, did not need to be included in the IFUs in accordance with the aforementioned law.

D. Dr. Flynn will not offer legal conclusions.

Dr. Flynn will not offer legal conclusions in this case. The only statement cited by Plaintiffs, "Ethicon has properly warned physicians of the adverse events" (TVT Report at 30), is not a legal conclusion. Under Plaintiffs' interpretation, the Court should preclude Plaintiffs' experts from testifying that Ethicon did not properly warn physicians of adverse events.

Respectfully Submitted,

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 1 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on this date, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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